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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

SCHWADRON, RONALD B

ART UNIT	PAPER NUMBER
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1644

DATE MAILED: 07/06/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/500,746

Applicant(s)

WINCHESTER ET AL.

Examiner

Ron Schwadron, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 18 and 19 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 18 and 19 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: ____.

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1. Claims 18 and 19 are under consideration.
2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 18 and 19 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Applicants arguments have been considered and deemed not persuasive.

Claim 18 is indefinite in the recitation of "indicated for treating rheumatoid arthritis" because it is unclear what this means or encompasses in the context recited in the claim. It is unclear if "indicated for treating rheumatoid arthritis" refers to an intended use or that it implies that there is some sort of label and/or instruction that communicates this intended use and that this label and/or instruction is supplied with the composition. Regarding applicants comments, the Examiner takes the position that while this term is indefinite, it could be interpreted as an intended use for the composition wherein the composition does not contain a label or instructions per se. Furthermore, use of common drugs for "off use" purposes is also found wherein the label or instructions do not communicate a common use. For example, low dose enteric coated aspirin is commonly used for its putative cardiac disease preventive properties, yet this use is not elucidated on the label or accompanying instructions.

Regarding applicants assertions regarding what the phrase under consideration means, there is no evidence of record to support applicants assertions. The MPEP section 2145, section I. (Page 2100-150, Rev. August 2001) discloses:

ATTORNEY ARGUMENTS CANNOT TAKE THE PLACE OF EVIDENCE

The arguments of counsel cannot take the place of evidence in the record. In re Schulze, 346 F.2d 600, 602, 145 USPQ 716, 718 (CCPA 1965). Examples of attorney statements which are not evidence and which must be supported by an appropriate affidavit or declaration include statements regarding unexpected results, commercial success, solution of a long-felt need, inoperability of the prior art, invention before the date of the reference, and

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allegations that the author(s) of the prior art derived the disclosed subject matter from the applicant.

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 18 and 19 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

There is no support in the specification as originally filed for the recitation of "indicated for treating rheumatoid arthritis" in claim 18. Regarding applicants comments about "composition for treating rheumatoid arthritis", this phrase implies that the composition is used for treating rheumatoid arthritis. It does not indicate that the composition has a label or instructions for treating rheumatoid arthritis. Said limitation indicates nothing more than an intended use. It is unclear if "indicated for treating rheumatoid arthritis" refers to an intended use or that it implies that there is some sort of label and/or instruction that communicates this intended use and that this label and/or instruction is supplied with the composition. To the extent that term indicates anything other than an intended use it constitutes new matter because there is no support in the specification as originally filed for the scope of the claimed invention (eg. the claimed invention constitutes new matter).

Regarding applicants comments about "composition for treating rheumatoid arthritis", this phrase implies that the composition is used for treating rheumatoid arthritis. It does not indicate that the composition has a label or instructions for treating rheumatoid arthritis. Said limitation indicates nothing more than an intended use. It is unclear if "indicated for treating rheumatoid arthritis" refers to an intended use or that it implies that there is some sort of label and/or instruction that communicates this intended use and that this label and/or

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instruction is supplied with the composition. To the extent that term indicates anything other than an intended use it constitutes new matter because there is no support in the specification as originally filed for the scope of the claimed invention (eg. the claimed invention constitutes new matter).

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 18 and 19 are rejected under 35 U.S.C. 102(a) as being anticipated by Schols et al.

The recitation of an intended use carries no patentable weight in the instant product claims. Schols et al. teach a bicyclam (AMD3100) and said compound in a carrier/pharmaceutically acceptable carrier (eg. media used to dissolve said compound or PBS)(see page 147 and page 149, second column, first complete paragraph and Figure 2).

Regarding applicants arguments, “indicated for treating rheumatoid arthritis” while indefinite for the reasons stated above is being interpreted as an intended use for the purposes of this product claim. The recitation of an intended use carries no patentable weight in the instant product claims. Furthermore, assuming arguendo that “indicated for treating rheumatoid arthritis” did indicate some sort of label or instructions, the CAFC recently ruled that such labels carry no patentable weight in a product claim. The court stated In Re Ngai (70 USPQ 2D 1862) CAFC that:

“Ngai is entitled to patent his invention of a new RNA extraction method, and the claims covering that invention were properly allowed. He is not, however, entitled to patent a known product by simply attaching a set of instructions to that product.”

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8. Claims 18 and 19 are rejected under 35 U.S.C. 102(b) as being anticipated by De Vreese et al. as evidenced by Schols et al.

The recitation of an intended use carries no patentable weight in the instant product claims. De Vreese et al. teach the bicyclam JM3100 and said compound in a carrier/pharmaceutically acceptable carrier (eg. media used to dissolve said compound)(see page 210 and section 2.3). Schols et al. disclose that JM3100 is another name for AMD3100 (see page 147, second column).

Applicants arguments are as addressed in paragraph 7 of this Office Action.

9. Claim 18 is rejected under 35 U.S.C. 102(b) as being anticipated by Murrer et al. (US Patent 5,021,409)

The recitation of an intended use carries no patentable weight in the instant product claims. The recitation of a method of making the claimed compound/composition carries no patentable weight in the instant product claims. Murrer et al. teach bicyclams in a carrier/pharmaceutically acceptable carrier (see column 1, third paragraph, column 2, penultimate paragraph and claims 7 and 8).

Applicants arguments are as addressed in paragraph 7 of this Office Action.

10. Claims 18 and 19 are rejected under 35 U.S.C. 102(b) as being anticipated by Datema et al. as evidenced by Schols et al.

The recitation of an intended use carries no patentable weight in the instant product claims. Datema et al. teach the bicyclam JM3100 and said compound in a carrier/pharmaceutically acceptable carrier at a variety of different concentrations (see page 751, column 2). Schols et al. disclose that JM3100 is another name for AMD3100 (see page 147, second column).

Applicants arguments are as addressed in paragraph 7 of this Office Action.

11. No claim is allowed.

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12. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ron Schwadron, Ph.D. whose telephone number is 571 272-0851. The examiner can normally be reached Monday through Thursday from 7:30 to 6:00. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan, can be reached on 571-272-0841. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



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Art Unit 1644